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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,405

06/30/2006

Eric E. Schadt

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SEATTLE, WA 98101-2347

EXAMINER

DEJONG, ERIC S

ART UNIT

PAPER NUMBER

1631

NOTIFICATION DATE

DELIVERY MODE

06/24/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efiling@cojk.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,405	<b>Applicant(s)</b> SCHADT ET AL.	
	<b>Examiner</b> ERIC S. DEJONG	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 72,86,126-159 and 168-202 is/are pending in the application.
- 4a) Of the above claim(s) 72,86,126-159 and 195-202 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 168-194 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/30/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED OFFICE ACTION**

Applicants response filed 03/18/2010 is acknowledged.

### ***Election/Restrictions***

Applicant's election without traverse of Group IV (claims 168-194) in the reply filed on 03/18/2010 is acknowledged.

Claims 1-71, 73-85, 87-125, and 160-167 are cancelled.

Claims 72, 86, 126-159, and 168-202 are pending.

Claims 72, 86, 126-159, 195-202 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to the nonelected Groups of Invention I-III, V, and VI, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/18/2010.

Claims 168-194 are currently under examination.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 06/30/2006 has been considered by the examiner.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 168-194 are rejected under 35 U.S.C. 101 because .the claimed invention is directed to non-statutory subject matter.

The recent en banc decision regarding *Bilski v. Warsaw* (2008) set forth that a process is patent-eligible if (1) it is tied to a particular machine or apparatus or (2) it transforms a particular article into a different state or thing. Further, the recent decision in *Comiskey* (2009) confirmed the opinion set forth in *Bilski* of the prohibition pre-empting an abstract idea or mental process in a claim. The revised *Comiskey* decision further reiterated the precedent set forth in *Richman*, 563 F.2d 1026, 1030 (CCPA 1977) wherein the court held the application unpatentable because “if a claim [as a whole] is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory.”

In the instant case, each independent claim is directed to a method identifying a molecular target. The recited process comprises only abstract steps directed to identifying genes, mapping genes, and determining therefrom a specified relationship between naturally occurring genetic loci of a segregated population. The recited process steps involve establishing a series of abstract correlations that purport to identify a naturally occurring relationship between a specified gene and markers mapped to identifiable genetic loci. Such amounts only to an expression of an abstract thesis as the instant claims do not recite any positive limitation wherein physical steps or interactions

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occur. A practitioner of the instant need not perform any physical act nor would said practitioner be required to interact in any definitive physical object or specified apparatus in a particular manner. As such, the instant claim lack both a tie to a particular machine or apparatus, nor do the involve any transformation of a particular article into a different state or thing. For these reasons, the claimed invention is directed to non statutory subject matter.

Claims 168-194 rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

In the instant case, each independent claim is directed to a method identifying a molecular target. The recited process comprises only abstract steps directed to identifying genes, mapping genes, and determining therefrom a specified relationship between naturally occurring genetic loci of a segregated population. The recited process steps involve establishing a series of abstract correlation that purport to identify a naturally occurring relationship between a specified gene and markers mapped to identifiable genetic loci. Such amounts only to an expression of an abstract thesis as the instant claims do not recite any positive limitation wherein physical steps or interactions occur..

However, the instant claims do not recite any particular improvement or resultant characteristic that is imparted to genes identified by the instant method or how analysis of the resultant sequences would be used to yield any useful information. The Court of Patent and Appeals has stated:

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"Practical utility is a shorthand way of attributing "real-world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." A 'use' to do further research is not considered a utility which provides an "immediate benefit" to the public.

Examples of situations requiring further research to identify or reasonably confirm a "real world" context of use, and which do not have utility under 35 USC 101, as set forth in MPEP 2107.01.1, include:

(A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved, and

(C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility.

The instant claims encompass a process of basic research drawn to studying properties of a protein structure and as such do not result in an "immediate benefit" to the public.

As noted in the utility guidelines (see Federal Register, December 21, 1999, Vol. 64, No. 244), basic research on a product to identify properties is an insubstantial utility (see page 6 of the Utility guideline training materials). Therefore, the instant claims do not have a substantial utility.

### ***Claim Rejections - 35 USC § 112, Enablement***

Claims 168-194 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. DEJONG whose telephone number is (571)272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ERIC S. DEJONG/  
Primary Examiner, Art Unit 1631